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Marc O. Schurr

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EXAMINER

EREZO, DARWIN P

ART UNIT

PAPER NUMBER

3773

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/957,451 | Applicant(s) SCHURR ET AL. | |
| | Examiner Darwin P. Erez | Art Unit 3773 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,5,7,120,121,124,126,127,129-132,134,135,137,138,140,142-145,147,148,150-155,157,164-167 and 172-181.

Continuation of Disposition of Claims: Claims rejected are 1,2,4,5,7,120,121,124,126,127,129-132,134,135,137,138,140,142-145,147,148,150-155,157,164-167 and 172-181.

DETAILED ACTION

1. The applicant's amendment filed on 6/5/08 has been entered into the application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claim 4 is rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites the limitation "wherein at least one of the first and second arms includes an additional anchoring portion including a fixation hole configured to receive an anchoring member." This limitation contradicts the newly added limitation in independent claim 1, which recites that "the other of the first and second arm does not include a structure for receiving the integral anchoring portion". Therefore, the claim is rendered vague and indefinite.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 2, 5, 7, 120, 121, 124, 126, 127, 129-131, 134, 135, 137, 138, 140, 142-144, 147, 148, 150-154, 157, 164-167, 172, 174, 176, 178, 180 and 181 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,604,425 to Le Roy in view of US 5,620,452 to Yoon.

(claims 1, 120, 135 and 148) Le Roy discloses a clip that is fully capable of securing a fold of tissue for treating GERD, the clip comprising:

a first arm (see attached figure below);

a second arm disposed substantially opposite from each other (see figure below),

wherein the first and second arms have a first end fixedly connected to each other to define an opening that is capable of receiving a fold of tissue (see figure below)

wherein the first and second arms is capable of extending substantially in the same direction as the fold of tissue (see figure below),

wherein the opening allows tissue to extend beyond a second end of the first and second arm (see figure below),

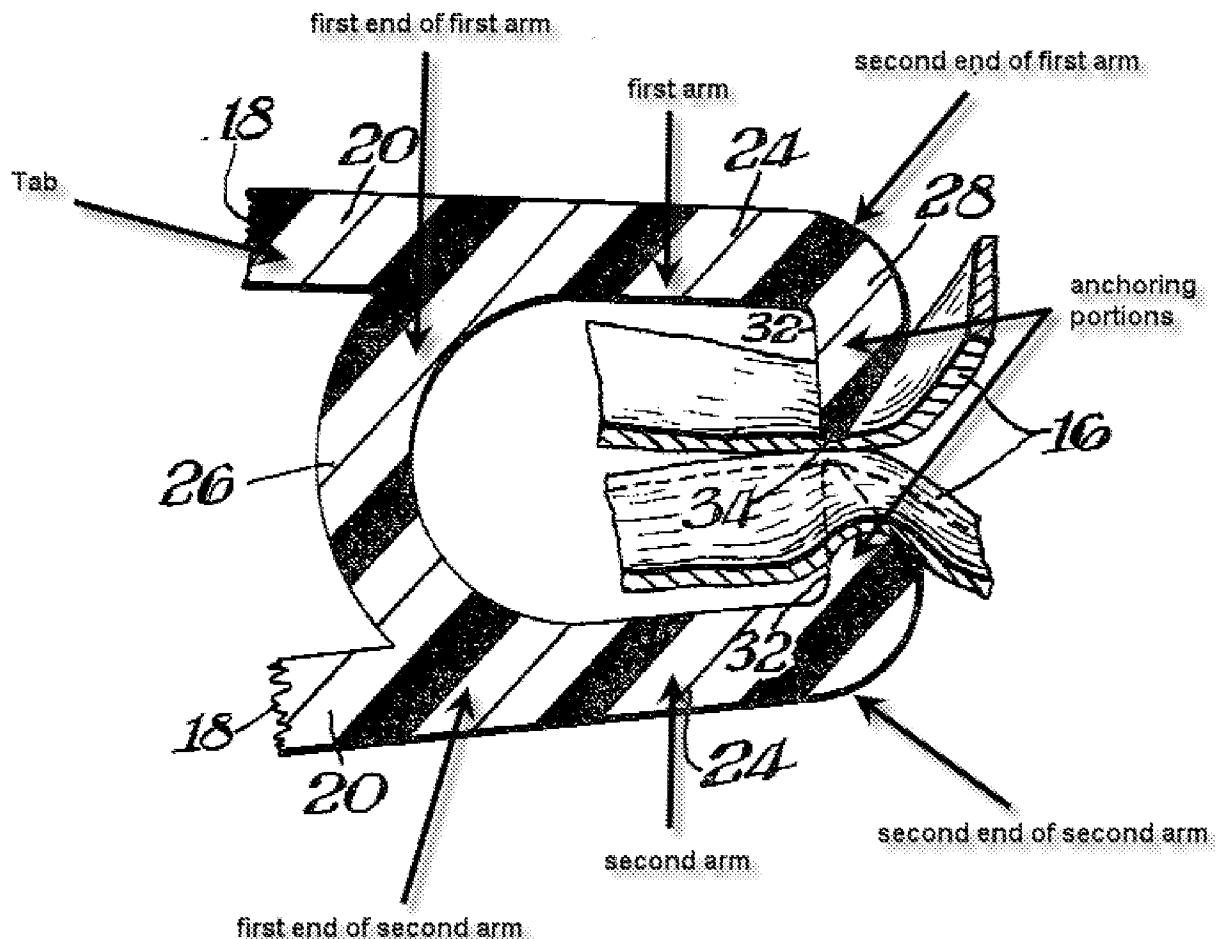
wherein the second ends of the first and second arms are capable of maintaining a non-contacting relationship when in a deployed stated (a tissue is located between the second ends of the first and second arm which would prevent the first and second arms from contacting),

wherein the second end of the first arm is configured to maintain a non-contacting relationship with the second end of the second arm when the device is in an initial, normal position (Fig. 3),

wherein the second arm **18** includes integral anchoring portions **50**, which are projections that are capable of maintaining a non-contacting relationship with the other of the first and second arms during a deployed state,

wherein the first and second arms are comprised of bioabsorbable material such that the entire clip, including the first and second arms, is capable of disintegrating in a body (col. 3, lines 40-41),

wherein the clip is fully capable of being inserted through an esophagus.



Le Roy discloses all the limitations of the claims except for the clip being made from bioabsorbable materials. However, the use of bioabsorbable materials in the manufacturing of surgical clips are well known in the art. For example, Yoon discloses a surgical clip that is made of bioabsorbable material (col. 3, ll. 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to manufacture the device of Le Roy with a bioabsorbable material since it would allow the clip to dissolve in the body without requiring an additional surgery for removal. Furthermore, it would be obvious to use bioabsorbable materials in devices implanted

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within a human body since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

(claim 2) The first and second arms are fully capable of frictionally engaging an outer surface of a tissue fold.

(claims 5, 131, 144 and 154) The clip includes a gripping tab, as shown in the figure above and in Figs. 1 and 3.

(claims 7, 134, 147 and 157) The first arm and second arm forms a substantially U-shaped configuration.

(claim 121) The anchoring portion is fully capable of engaging a fold of tissue therebetween.

(claims 124, 137, 138, 150-152, 172, 174, 176 and 178) The anchoring portion is viewed as a reverse angle barb projection. As shown in the figure above, the anchoring portion is barb-like with an angle that can be viewed as reversed.

(claims 126, 127, 140, 180 and 181) The anchoring portion includes two projections that are located directly opposite to one another along the first and second arms (see figure above).

(claim 129 and 142) The additional anchoring member (either of the first and second arm) has a tip that can be called a pin that is capable of piercing tissues.

(claims 130, 143, 153) The distal end of each arm includes the anchoring portions, which tapers away from the gap.

(claims 164-167) The clip of Le Roy is fully capable of not being removed, especially after being modified to be made of a bioabsorbable material.

8. Claims 132, 145, 155, 173, 175, 177 and 179 are rejected under 35 U.S.C. 103(a) as being unpatentable over Le Roy in view of Yoon, as applied in the rejections above, and in view of US 3,032,039 to Beaty.

The modified device of Le Roy discloses all the limitations of the claims except for the distal ends of the first and second arm having the tab defining a crook. Instead, Le Roy discloses tabs located in the proximal end. However, the use of tabs on a distal end of surgical clips are well known in the art, as disclosed by Beaty (see Figs. 1-3). The tabs on the distal end also allow the clips to be manipulated by an applicator. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Le Roy to have the tabs be located on the distal end tabs because such arrangement is well known in the art. Furthermore, the arrangement taught by Beaty is an equivalent structure for manipulating a clip so one of ordinary skill in the art would have found it obvious to substitute a tab on the distal end for the tab on the proximal end since it would yield predictable results (both allow manipulation of the clip) *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

Response to Arguments

9. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/
Primary Examiner, Art Unit 3773